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RUEHCV/AMEMBASSY CARACAS PRIORITY 1670  
RUEHLP/AMEMBASSY LA PAZ FEB 5689  
RUEHPE/AMEMBASSY LIMA PRIORITY 5457  
RUEHMN/AMEMBASSY MONTEVIDEO PRIORITY 3922  
RUCPDO/DEPT OF COMMERCE WASHDC PRIORITY  
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UNCLAS SANTIAGO 000167

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STATE FOR WHA/BSC AND EB/TPP/IPE - JENNIFER BOGER  
STATE PLEASE PASS TO USTR - KDUCKWORTH AND CWILSON  
COMMERCE FOR KRISTEN MANN

E.O. 12958: N/A  
TAGS: [KIPR](#) [ETRD](#) [PREL](#) [PGOV](#) [CI](#)  
SUBJECT: CHILE: POST RECOMMENDS CHILE REMAIN ON PRIORITY  
WATCH LIST

REF: STATE 9475

¶1. (SBU) Summary: Post recommends Chile remain on the Special 301 Priority Watch List (PWL) in 2008. In January 2007, Chile was placed on the PWL following an Out-of-Cycle Review (OCR) and it remained there for all of 2007. The GOC does not like being on the PWL, and the stick has provided motivation inside the government to begin work to improve its framework for the protection of intellectual property rights. That being said, all that work remained in the draft stage during 2007. The most significant step was the introduction of draft legislation in May 2007 on trademarks and copyrights. This bill remains in Congress, with passage likely in 2008. Little has been done on other issues such as joining the Patent Cooperation Treaty (part of Chile's Free Trade Agreement obligations to the U.S.) and improving protection of pharmaceutical patents and proprietary clinical data. Finally and most tellingly, there remains no clear national policy on intellectual property rights. End Summary.

Priority Watch List Background  
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¶2. (SBU) In 2006, the third year of the U.S.-Chile Free Trade Agreement (FTA), Chile was the subject of an Out-of-Cycle Review (OCR) due to its failure to fulfill many FTA commitments on the protection of intellectual property rights (IPR). The OCR, announced in April 2006, resulted in an intensified and generally positive dialogue between U.S. and Chilean officials. During the course of that dialogue, the GOC was unable to explain its institutional framework to protect IPR, essentially laying bare the lack of protection. On January 8, 2007, the Office of the U.S. Trade Representative (USTR) announced the results of the OCR and placed Chile on the Priority Watch List (PWL) for the first time. Placing Chile on the PWL led to an immediate and sustained public debate on IPR, which almost exclusively favored more robust IPR protection. Before the regular annual Special 301 review and announcement in April 2007, there were no significant changes, and Chile remained on the PWL for all of 2007.

¶3. (SBU) One of the four declared pillars of President

Bachelet's administration (she began a four-year term in March 2006) is innovation. She appointed a presidential council, headed by a former finance minister, to identify potential value-added sectors for the GOC to promote. Thanks to Bachelet's emphasis on the subject, there is a great deal of talk inside the GOC and in the public domain about the importance of innovation. That being said, to date that talk has remained largely just rhetoric and there has not been much concrete action to back up the words. At an elementary level, Chileans understand that improved IPR protection is a key part of fostering innovation and creating value-added sectors in the economy. But, the GOC is struggling to find practical ways to turn its talk into deeds.

#### Data Protection and Patent Linkage

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¶4. (SBU) Since the FTA went into force in January 2004, there has been no institutional progress on core issues such as data protection and patents related to pharmaceutical products. Despite new legislation and implementing regulations dating back to 2005, Chile has continued to grant approval for generic copies, which violate patents for innovative pharmaceuticals. Additionally, the GOC has exhibited a pattern of allowing local companies to use exclusive company data from innovative Asian, European and North American companies as the scientific basis for granting sanitary (and thus market) approval for these generic copies.

International pharmaceutical companies continue to detail violations of exclusive company test data in the Chilean drug approval process.

¶5. (SBU) On the issue of patents, there is no linkage between granting market access and the existence of valid patents.

The GOC has consistently maintained that it provides linkage through the judicial system and that the dispute over linkage is a difference of interpretation as to the specific obligations in the U.S.-Chile FTA. A French pharmaceutical company enjoyed one minor and partial legal victory in 2007 in a case against a Chilean firm over a patent violation. The case was lengthy, the fine was minimal (USD 6,000) and the offending drug was not pulled from the market. It's hard to see how the courts provide linkage in Chile.

#### Dancing Sideways on Clinical Data

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¶6. (SBU) In July 2006, the Instituto de Salud Publica (ISP) -- the rough equivalent of the FDA -- issued an internal regulation, which required any company seeking approval for a biotech product to submit its own proprietary clinical test data. This was viewed by innovative pharmaceutical companies as a clear step forward in better protecting their clinical data and, hopefully, eventually their valid patents as well. By December 2006, in what has been privately described to us as part of an internal turf battle at the ministry, Minister of Health Barria overruled and removed the ISP regulation. Though there has been informal talk of Minister Barria re-issuing these rules under her own authority, over a year later nothing has happened.

¶7. (SBU) As a further twist, new data protection rules were briefly published on the Ministry of Health's website in January 2008, only to be removed within days for "further drafting." The official GOC explanation is that the rules were published for public comment. The unofficial explanation is that they were removed due to pressure from Chilean pharmaceutical firms which saw the rules as disadvantageous. What was briefly exposed to public view was largely in line with the ISP's initial regulation from July 2006 and represented some improvement over existing norms. If something along these same lines were to be issued as a Ministry of Health decree, it could represent an advance in providing protection to proprietary clinical data. However, it appears that once again everything is on hold.

#### Piracy and Legislation on Copyrights and Trademarks

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¶18. (SBU) In the aftermath of being placed on the PWL, there was a burst of activity on the public anti-piracy front. Illegal copies of music, movies and books were seized, which made some headlines. There has been a campaign to remove illegal copies from Santiago, but this has largely meant moving vendors rather than prosecuting them. Overall, industry and anecdotal evidence suggests nothing has substantively changed. If anything, the pirates' understanding of the market is more sophisticated and developed than ever. On Santiago's streets, prices for pirated software, music and films have dropped, implying greater supply. Additionally, the pirated market has become more sophisticated and segmented, with vendors increasingly catering to specific tastes and clientele rather than selling a little bit of everything.

¶19. (SBU) There was a substantive anti-piracy reform package introduced by Bachelet with great fanfare in May 2007. The reform package was far from perfect but represented an advance in developing a more practical IPR protection framework. Additionally, the bill was supported by eight different Chilean ministries. While not reason alone to cheer, this development showed the degree to which interest in and concern about IPR have spread inside the GOC. Three years ago, the Ministry of Foreign Affairs was a lone voice inside the GOC as it transmitted U.S. and European concerns about IPR violations to other ministries.

¶110. (SBU) In the course of 2007, as the bill worked its way through Congress, the GOC was receptive to a positive and sustained dialogue with the U.S. on suggested changes to the legislation. This dialogue included formal meetings, such as

the FTA's annual Free Trade Commission talks in November, informal exchanges via phone and e-mail and most substantively through a series of three digital video conferences (DVCs). These DVCs brought together technical experts and allowed the U.S. to make clear its concerns with parts of the draft legislation. Chile's Congress will likely pass the law in the first half of 2008 but to what degree the final version will reflect U.S. concerns is unclear. Whatever legislation is passed will, of course, be followed by the equally important phases of implementing regulations and then enforcement. We are still far from being able to pass judgment on outcome of this reform package.

Core Problem: No Policy on IPR

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¶111. (SBU) As noted in previous years, the core issue at the heart of IPR-related issues in Chile is the lack of a clear government policy. Chile has a strong presidential system, and individual ministries cannot on their own make policy on IPR. Unambiguous direction must come from the top and that means President Bachelet. Though the judiciary is independent, it also part of the same system and sees there is no clear policy direction. As such, judges drag out court cases to the point of irrelevancy, make minor decisions as in the one legal victory in 2007 for an innovative pharmaceutical company, or find unrelated technical reasons for dismissal. While the public debate favors greater IPR protection, and ministries are increasingly educated and engaged on the issue, the system as a whole is waiting on leadership from the top. So far, that has not come.

Recommendation: Maintain Chile on the Priority Watch List

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¶112. (SBU) Though 2007 was more positive for IPR in terms of dialogue and tone than previous years, Chile continues to fall far short of its rhetorical and practical commitments to its trade agreements. Placing Chile on the PWL in January 2007 was the right thing to do based on the facts. It proved also a smart move in terms of generating a public debate on IPR. As noted, that debate has favored improved protection and furthered understanding of the link between fostering

innovation and IPR protection. The stick of being on the PWL continues to motivate the GOC to take actions to remove itself from this list. Removing Chile from the PWL in 2008 would a mistake on every front. We have the potential over the coming few years to move substantively and sustainably in the right direction on IPR in Chile. To do that, we will need to keep up the pressure.

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